

**ASPIRIN 81 MG- aspirin tablet, coated**  
**Health Pharma USA LLC**

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**Aspirin 81 mg Tablets**

***Active ingredient***  
***(in each tablet)***

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

***Uses***

for the temporary relief of minor aches and pains or as recommended by your doctor

***Warnings***

**Reye's syndrome:**Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:**Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

**Stomach bleeding warning:**This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older

**Do not use**

if you are allergic to aspirin or any other pain reliever/fever reducer.

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

taking a prescription drug for

- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - vomit blood
  - have bloody or black stools
  - feel faint
  - have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?**

**(844) 832-1138**

**Principal Display Panel**



**Health Pharma USA LLC**

1600 Hart Street, Rahway, NJ 07065

Phone: 732-540-8421

**BULK LABEL \_\_\_\_\_ of \_\_\_\_\_**

**PRODUCT NAME: Aspirin 81 mg Enteric Coated Yellow Tablet (Logo "A1 ")**

**PRODUCT CODE # PC010**

**LOT #**

**Labeler code – 71679-010-00**

**NET WEIGHT (KG)**

**Tablets/BOX**

**18.00**

**155,850**

**BULK PACKAGING:** 2 MIL clear Polyethylene Bag in Brown Flute Double Wall Corrugated Boxes.

**BULK PRODUCT:** Package immediately upon receipt

**WARNING:** Keep out of Children. This bulk shipment is intended for further processing only. Repackage contents as soon as possible. This is a shipping container only and will not protect contents from damage by heat, cold and moisture indefinitely. Manufacturer will not accept responsibility for spoilage or violations of the food, Drug and cosmetic act due to prolonged storage in this container. Contents must be repackaged prior to resale and must be labeled in full compliance with the requirement of the Food, Drug and Cosmetic Act.

**STORAGE:** Store at a controlled room temperature 15-30°C (59-86° F)

**ASPIRIN 81 MG**

aspirin tablet, coated

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:71679-010

**Route of Administration**

ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>ETHYL ACRYLATE</b> (UNII: 71E6178C9T)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>METHACRYLIC ACID</b> (UNII: 1CS02G8656)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	S1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-010-00	1 in 1 DRUM	05/01/2011	
1		25000 in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2011	

**Labeler** - Health Pharma USA LLC (080804485)